REMARKS

Claims 1-40 were pending in the present application. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35 and 37-40 have been rejected and claims 7, 10, 17, 23, 29, and 36 have been withdrawn from consideration. By virtue of this response, claims 2, 15, and 18-38 have been cancelled, claims 1, 3, 5, 7, 10, 17, 39, and 40 have been amended and new claims 41-60 have been added. Accordingly, claims 1, 3-6, 8, 9, 11-14, 16, and 39-60 are currently under consideration.

Interview Summary

An interview with Examiner Ewoldt was held by telephone on May 23, 2007. In addition to Examiner Ewoldt and Alicia Hager (the undersigned), Matt Linnik and Catherine Polizzi participated in the interview. Applicants and their representatives would again like to thank Examiner Ewoldt for the courtesy of the telephonic interview.

The subject of the telephonic interview was the Office Action dated January 30, 2007. Claims discussed included claims 1 and 39. In addition, the reference cited in the Office Action, WO 01/41813, was discussed. The Examiner's objection to the title was also discussed. In addition, corrections to certain sequences in the specification and claims were proposed and discussed. The sequence-related corrections that were discussed during the interview are reflected in the sequence-related amendments in the specification and claims contained herein.

Election of Species and Withdrawal of Claims 7, 10, and 17

Applicants would like to point out that a sequence error in one of the elected species has now been corrected. In addition, Applicants believe that withdrawn claims 7, 10, and 17 are actually drawn to elected subject matter, and request rejoinder and examination of these claims.

Although Applicants previously elected a dsDNA epitope comprising "a double-stranded polynucleotide 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1) in combination with its complementary strand" (page 2 of Response to Restriction/Election of Species Requirement filed November 14, 2006), SEQ ID NO:1 has now been corrected throughout the specification and claims

to correctly read "5'-TGTGTGTGTGTGTGTGTGTG-3' (SEQ ID NO:1)" or the equivalent. The basis for these amendments is provided in detail below under "Amendments to the Specification."

Applicants further elected "a dsDNA epitope which is administered in the form of a conjugate such as that set forth in claim 7." See page 2 of Response to Restriction/Election of Species Requirement filed November 14, 2006.

In the presently outstanding Office Action mailed January 30, 2007, the Examiner withdrew claims 7, 10, 17, 23, 29, and 36 as being drawn to non-elected species. "$(CA)_{10}$•$(TG)_{10}$" as recited in withdrawn claims 7, 10, and 17 is intended to indicate 5'-$(CA)_{10}$-3' (SEQ ID NO:2) annealed to 5'-$(TG)_{10}$-3' (SEQ ID NO:1). Accordingly, Applicants contend that claims 7, 10, and 17 are not drawn to a non-elected species and request that claims 7, 10, and 17 be rejoined and examined.

Amendments to the Specification

The specification has been amended at paragraphs [0010], [0013], [0066], [0070], [0122], [0123], [0231], [0232], and [0277] to recite sequence identification numbers and to correct a typographical error in the sequences.

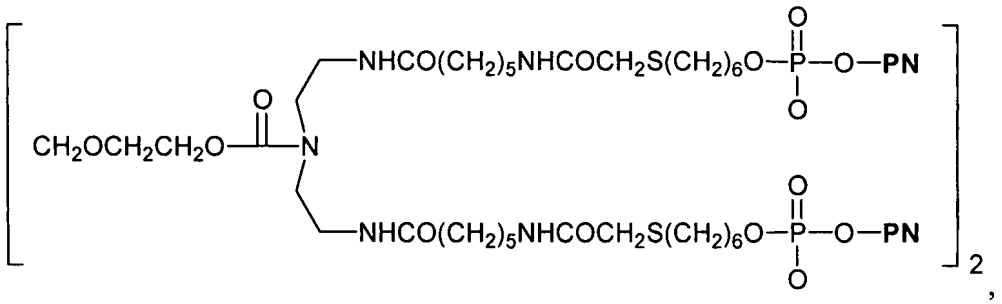
Support for the amendments that clarify the correct polynucleotide sequences of LJP 394, may be found, for example, in paragraph [0277] at pages 94-95 and in paragraph [0066] at pages 16-17. For instance, paragraph [0277] states that "[a] description of the synthesis of the conjugate LJP 394, a tetravalent conjugate, is described in Jones et al. (1995) and in U.S. Patent 5,552,391, which are hereby incorporated by reference." The reference "Jones et al. (1995)" is Jones et al., J. Med. Chem (1995) 38:2138-44, as indicated in lines 17-20 of paragraph [0011] at pages 4-5 of the specification. Jones et al. (1995) and U.S. Patent No. 5,552,391 disclose the polynucleotide sequences of LJP 394. See, e.g., Figure 6B, Example 7, lines 42-43 of column 76, and line 66 of column 8 to line 1 of column 9 of U.S. Patent No. 5,552,391. Based on these disclosures, one of ordinary skill in the art would have recognized that the correct and intended polynucleotide sequences are the sequences reflected in the amendments to the specification and claims.

No new matter is added.

Claim Amendments

Claims 2, 15, and 18-38 have been cancelled, claims 1, 3, 5, 7, 10, 17, 39, and 40 have been amended, and new claims 41-60 have been added. No new matter is added.

Claims 1, 39, and 40 are amended to recite, "wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the individual." Support for this amendment is found, e.g., in lines 10-13, 16-18, 24-27, and 29-31 of paragraph [0119] at pages 75-76 of the specification. Applicants note that a 200 mg dose for a person of standard weight between 60 and 70 kg is equivalent to about 3 mg/kg.

Claims 1, 39, and 40 are further amended to recite, "wherein administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month." Support for these amendments is found, e.g., in original claim 2 and in lines 11-13 of paragraph [0084] at page 26.

Claims 1, 39, and 40 are still further amended to replace "an individual" with "a human individual." Support for these amendments is found, e.g., in original claim 15, as well as in paragraph [0030] at page 11 of the specification.

Claim 39 is still further amended to replace "a treatment" with "an effective amount of a dsDNA epitope." Support for this amendment is found throughout the application, including, for example, in paragraph [0031] at page 11.

Claim 3 is amended to refer to claim 1, rather than claim 2, due to the amendment of claim 1 and cancellation of claim 2.

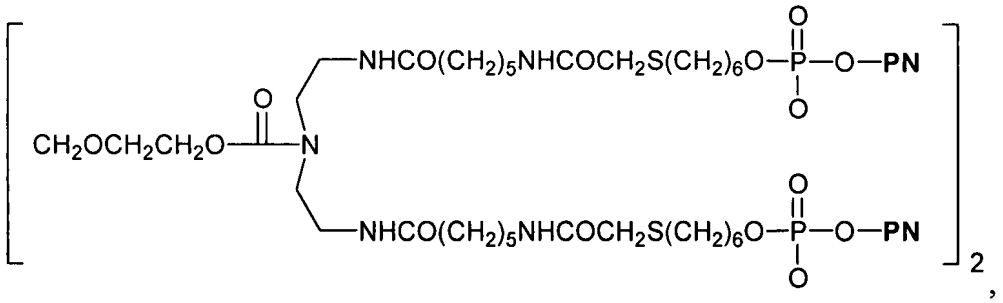
Claim 5 has been amended to correct typographical errors to clarify the orientation of the recited polynucleotide sequences. Support for this amendment is found, e.g., in paragraph [0277] at pages 94-95 and in paragraph [0066] at page 16, as explained above under "Amendments to the Specification."

Claims 7, 10, and 17 have been amended to add sequence identifiers.

New dependent claim 41 finds support, e.g., in lines 10-12 of paragraph [0119] at pages 75-76 of the specification.

New dependent claim 42 finds support, e.g., in lines 29-31 of paragraph [0119] at pages 75-76 of the specification.

New independent claim 45 directed to a "method of stabilizing or improving the health-related quality of life of a human individual with systemic lupus erythematosus (SLE), comprising administering to the individual an effective amount of a dsDNA epitope which specifically binds to an anti-dsDNA antibody from the individual, wherein the administration of the dsDNA epitope results in a stabilization of or improvement in the individual's health-related quality of life, wherein the administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and wherein if the dsDNA epitope is administered weekly to the individual in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), the dsDNA epitope is administered to the individual for a period of more than about 16 consecutive weeks," finds support, e.g., in original claims 9 and 10, paragraph [0010] at page 4, paragraph [0030] at page 11, paragraph [0070] at page 19, paragraph [0084] at pages 25-26, and lines 7-11 of paragraph [0221] at page 77.

New dependent claims 43 and 51 recite that the "sustained reduction is at least about 20% below baseline. New dependent claims 44 and 52 recite that the "sustained reduction is at least about 30% below baseline. Support for new claims 43, 44, 51, and 52 is found, e.g., in paragraph [0027] at page 10, and in lines 27 to 28 of paragraph [0084] at page 26.

New dependent claims 46-48 find support, e.g., in paragraph [0070] at page 19-20.

New dependent claim 49 finds support, e.g., in lines 7-12 of paragraph [0161] at pages 52-53.

New dependent claim 50 finds support, e.g., in paragraph [0030] at page 11 and in paragraph [0103] at page 34.

New independent claim 55, finds support, e.g., in original claims 1, 2, and 7, in lines 11-13 of paragraph [0084] at page 26, and in lines 10-13, 16-18, 24-27, and 29-31 of paragraph [0119] at pages 75-76 of the specification. As noted above, a 200 mg dose for a person of standard weight between 60 and 70 kg is equivalent to about 3 mg/kg.

New dependent claims 53 and 56 find support, e.g., in lines 10-12 of paragraph [0119] at pages 75-76 of the specification. New dependent claims 54 and 57 find support, e.g., in lines 29-31

of paragraph [0119] at pages 75-76 of the specification. New dependent claims 58 and 59, find support, e.g., in lines 16-18 of paragraph [0119] at pages 75-76 of the specification.

New independent claim 60 finds support, e.g., in original claim 10, paragraph [0010] at page 4, paragraph [0030] at page 11, paragraph [0070] at page 19, paragraph [0084] at pages 25-26, and lines 7-11 of paragraph [0221] at page 77.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

Objection to Title of Specification

The Examiner has objected to the title because it allegedly does not adequately describe the claimed invention.

In response, Applicants have amended the title to specifically recite that the methods involve the administration of dsDNA epitopes. Accordingly, Applicants respectfully request withdrawal of the objection to the title.

Claim Rejection under 35 U.S.C. § 112

Claim 39 is rejected under 35 U.S.C. § 112, second paragraph, for allegedly "being incomplete for omitting essential steps, such omission amounting to a gap between the steps." The Examiner states, "The omitted steps comprise some sort of recitation of what the treatment comprises."

Applicants respectfully traverse and disagree with the Examiner's statements regarding claim 39. Nevertheless, in the interest of expediting prosecution of this application and without

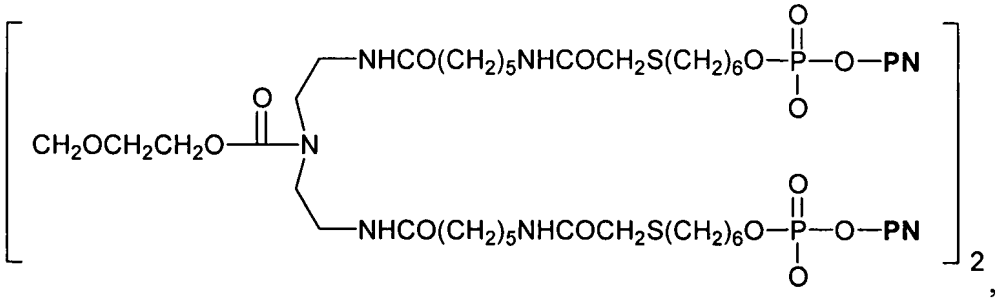
acquiescing as to the merits of the rejection, claim 39 has now been amended to specifically recite that a dsDNA epitope is administered to the selected individual.

Applicants respectfully request withdrawal of the rejection of claim 39 under 35 U.S.C. § 112, second paragraph.

Claim Rejection under 35 U.S.C. § 102(b)

Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35 and 37-40 are rejected under 35 U.S.C. § 102(b) as being anticipated by WO 01/41813. Applicants respectfully traverse this rejection. Because these claims have been amended, Applicants will focus on points of distinction with respect to the amended claims. However, Applicants note that points of patentable distinction also apply with respect to the claims before amendment.

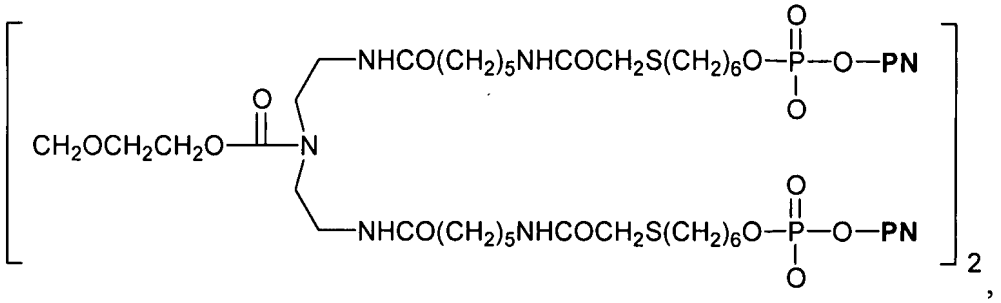
Independent claim 1, as amended, is directed to a method of stabilizing or improving the health-related quality of life of a human individual with systemic lupus erythematosus (SLE), comprising administering to the individual an effective amount of a dsDNA epitope which specifically binds to an anti-dsDNA antibody from the individual, wherein the administration of the dsDNA epitope results in a stabilization of or improvement in the individual's health-related quality of life, wherein administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the

individual. Dependent claims 3-6, 8, 9, 11-14, and 16 directly or indirectly depend upon claim 1 and therefore incorporate all limitations of claim 1.

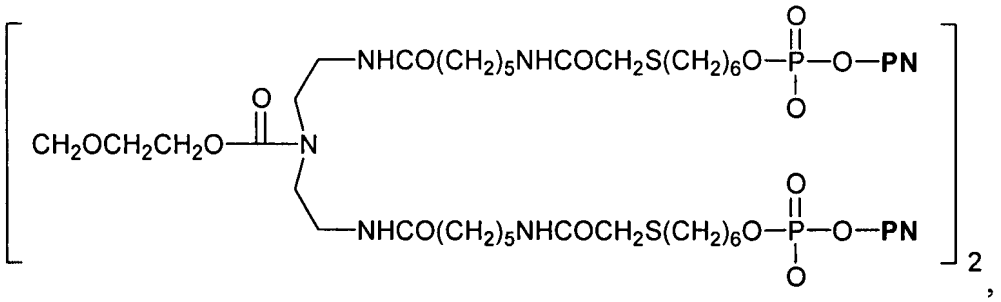
Independent claim 39, as amended, is directed to a method of stabilizing or improving the health-related quality of life in a human individual with SLE comprising the steps of: (a) selecting an individual for receiving or continuing to receive treatment based on the individual's need for a stabilized or improved health-related quality of life; and (b) administering an effective amount of a dsDNA epitope to the selected individual, wherein administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, and wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is $(CA)_{10}\bullet(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the individual.

Independent claim 40, as amended, is directed to a method of stabilizing or improving the health-related quality of life in a human individual having SLE comprising the steps of: (a) selecting an individual to receive or continue to receive a dsDNA epitope based on the affinity of the dsDNA epitope for an anti-dsDNA antibody in the individual; and (b) administering an effective amount of the dsDNA epitope to the selected individual, wherein administration of the dsDNA epitope stabilizes or improves the health-related quality of life in an individual, wherein administration of the dsDNA epitope results in a sustained reduction of the level of circulating anti-

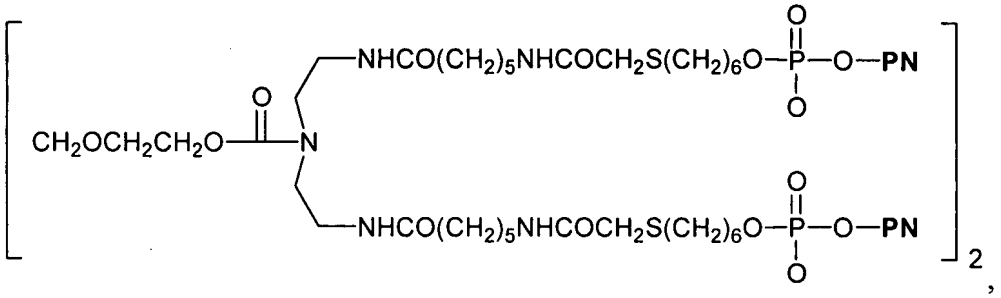
dsDNA antibodies in the individual that is maintained for at least about one month, and wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), the administration of the dsDNA epitope comprises administering a weekly dose of about 3 mg/kg or higher of the conjugate to the individual.

Claims 2, 15, and 18-38 have been cancelled, without prejudice, by virtue of this Amendment. Accordingly, the rejection with respect to these claims is moot.

To anticipate a claim, a prior art reference must teach or suggest each and every limitation of the claim. Applicants respectfully submit that WO 01/41813, if applied to the claims as amended, does not anticipate the claims, because WO 01/41813 fails to teach or suggest all elements of the claims. For instance, WO 01/41813 fails to teach or suggest administration of a dsDNA epitope to an individual that results in a *sustained* reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), the administration of the dsDNA epitope comprises administering *a weekly dose of about 3 mg/kg or higher* of the

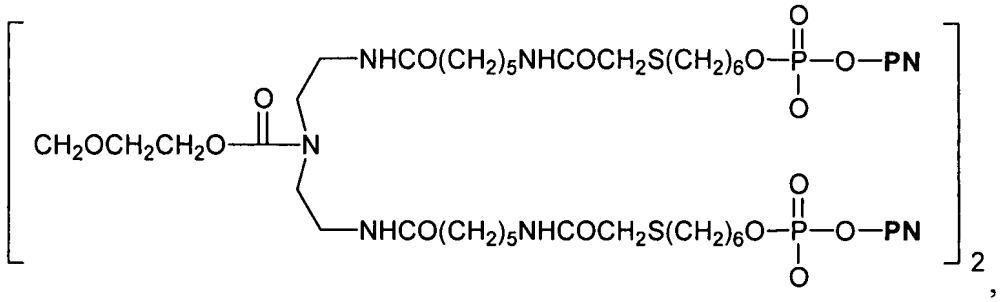
conjugate to the individual. In addition, WO 01/41813 fails to teach or suggest methods of stabilizing or improving the health-related quality of life of an individual with SLE. Even if WO 01/41813 teaches "sustained reduction of symptoms for at least about 24 weeks" and/or "stabilization after renal flare" as stated by the Examiner, the effects taught in WO 01/41813 cannot be simply summarily equated with "stabilizing or improving health-related quality of life."

Since WO 01/41813 does not teach or suggest each and every element of claims 1, 3-6, 8, 9, 11-14, 16, and 39-40, as amended, Applicants respectfully request that the rejection of these claims under 35 U.S.C. § 102(b) be withdrawn.

Obviousness-Type Double-Patenting Rejections

1. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35 and 37-40 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-64 of U.S. Patent No. 7,081,242. Applicants respectfully traverse this rejection. Because these claims have been amended, Applicants will focus on points of distinction with respect to the amended claims. However, Applicants note that points of patentable distinction also apply with respect to the claims before amendment.

Applicants submit that claims 1, 3-6, 8, 9, 11-14, 16, and 39-40 are not obvious over claim 1-64 of U.S. Patent No. 7,081,242. For instance, claims 1-64 of U.S. Patent No. 7,081,242 do not teach or suggest administration of a dsDNA epitope to an individual that results in a *sustained* reduction of the level of circulating anti-dsDNA antibodies in the individual that is maintained for at least about one month, wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), the administration of the dsDNA epitope comprises administering *a weekly dose of about 3 mg/kg or higher* of the conjugate to the individual. In addition, claims 1-64 of U.S. Patent No. 7,081,242 do not teach or suggest methods of stabilizing or improving the health-related quality of life of an individual with SLE. "Stabilizing or improving health-related quality of life" cannot be equated with "treatment of SLE.".

The remaining rejected claims, claims 2, 15, and 18-38, have been cancelled, without prejudice, by virtue of this Amendment. Accordingly, the rejection with respect to these claims is moot.

Applicants respectfully request that the rejection of these claims under the judicially created doctrine of obviousness-type double patenting be withdrawn.

2. Claims 1-6, 8, 9, 11-16, 18-22, 24-28, 30-35 and 37-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-26 of U.S. Patent Application No. 10/814,555, claims 1-39 of U.S. Patent Application No. 11/081,309, claims 1-27 of U.S. Patent Application No. 11/347,426, claims 1-21 and 34-55 of U.S. Patent Application No. 11/373,699, claims 1-26 of U.S. Patent Application No. 11/565,467, and claims 1-21 and 34-55 of U.S. Patent Application No. 11/613,987.

Without acquiescing as to the merits of the provisional rejection, Applicants respectfully request that, since none of the allegedly conflicting claims in copending Patent

Application Nos. 10/814,555, 11/081,309, 11/347,426, 11/373,699, and 11/565,467 have issued, these provisional rejections under the judicially created doctrine of obviousness-type double patenting be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 252312007900. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: July 30, 2007

Respectfully submitted,

By _____
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